CLAIMS

1. A method for treating diabetes in a mammalian subject in need of same wherein the method comprises:

administering to the mammalian subject an agent capable of modulating a ganglioside GM-1 (GM-1) associated activity in an amount effect to treat the disease;

wherein the agent, when *in vivo*, has an effect on GM-1 mediated intracellular signalling events; and

wherein if the agent is for co-administration with an antigen, then the agent and the antigen are not so linked to form a single active agent.

2. A method according to claim 1 wherein the effect on GM-1 mediated intracellular signalling events is due to an agent having GM-1 binding activity.

3. A method according to claim 1 wherein the agent is an immunomodulator.

4. A method according according to claim 3 wherein the agent is selected from the group consisting of Ctx, Etx, the B subunit of Ctx and the B subunit of Etx and mutants and derivatives thereof.

5. A method according to claim 1 wherein the agent is for co-administration with an antigen selected from the group consisting of self or cross-reacting antigen, alloantigen and xenoantigen.

6. A method according to claim 1 wherein the agent is for co-administration with an autoantigen.

7. A method according to claim 5 wherein the autoantigen is insulin.

8. A method according to claim 1 wherein the agent, when *in vivo*, is capable of modulating lymphocyte populations.

9. A method according to claim 1 wherein the agent, when *in vivo*, is capable of acting as a vaccine adjuvant.

10. A pharmaceutical composition comprising an agent as defined in claim 1 and a pharmaceutically acceptable carrier(s), diluent(s), excipient(s) or adjuvant of any combination thereof.

11. A composition according to claim 10 wherein the composition is for nasal administration.

12. A composition according to claim 10 wherein the composition is for oral administration.

13. A method for modulating an immune response in a mammalian subject in need of prevention against or treatment of diabetes wherein the method comprises administering to the mammalian subject an effective amount of an agent as defined in any one of the preceding claims wherein if the agent is for co-administration with an antigen, then the agent and the antigen are not so linked to form a single active agent.

14. A method according to claim 13 wherein the modulation of the immune response is determined by measuring a change in at least one parameter selected from the group consisting of: a change in Th2 asociated cytokine levels, a change in antigen specific T-cell reactivity, a change in Th1 associated cytokine levels and any combination thereof.

15, A method according to claim 14 wherein the agent decreases the production of Th1 associated cytokines.

16. A method according to claim 15 wherein the Th1 associated cytokine is IFNγ.

17. A method according to claim 14 wherein the agent increases the production of Th2 associated cytokines.

18. A method according to claim 17 wherein the Th2 associated cytokine is selected from the group consisting of IL-4 and IL-10 cytokines and any combination thereof.

19. A method according to claim 13 wherein the agent is capable of preventing the onset of insulin dependent diabetes mellitus (IDDM).

20. A method according to claim 19 wherein the agent, when *in vivo*, is co-administered with an autoantigen.

21. A method according to claim 20 wherein the autoantigen is selected from the group consisting of GAD, GAD65, IAA and insulin.

22. A method according to claim 20 wherein the agent is EtxB.

23. A method according to claim 13 wherein the agent is capable of treating pancreatic islet inflammation or for reducing the incidence of IDDM.

24. A method according to claim 23 wherein the agent is EtxB.

25. An assay method for identifying an agent useful in the prevention against and/or treatment of diabetes wherein the assay method comprises:

(i) contacting a test agent with a ganglioside receptor wherein the agent is not linked to an antigen

(ii) determining whether the agent modulates a ganglioside associated activity by measuring a change in at least one parameter selected from the group consisting of: a change in specific T cell reactivity, a change in Th1

associated cytokine levels; a change in Th2 associated cytokine levels and any combination thereof; and

(iii) identifying the useful agent by observation of modulation of ganglioside associated activity.

26. A method according to claim 25 wherein the agent binds to GM-1 ganglioside receptors.

27. A method according to claim 26 wherein the agent is selected from the group consisting of Ctx, Etx, CtxB, EtxB and mutants or derivatives thereof that bind to GM-1.

28. A method according to claim 25 wherein the agent has an effect on GM1 mediated intracellular signalling events but no GM1 binding activity.

29. A method according to claim 25 wherein the agent is capable of promoting an immune deviation away from Th1 associated cytokines and towards Th2 associated cytokines.

30. A method according to claim 25 wherein the agent is capable of promoting a suppression of a Th1 response.

31. The use of an agent in the preparation of a medicament to prevent and/or treat a diabetic condition;

wherein the agent is capable of modulating a ganglioside GM-1 (GM-1) associated activity;

wherein if the agent is for co-administration with an antigen, then the agent and the antigen are not so linked to form a single active agent; and

wherein the modulation of the ganglioside associated activity affects the diabetic condition.

32. The use according to claim 31wherein the modulation of the GM-1 associated activity is determined by measuring a change in at least one parameter selected from the group consisting of: a change in Th2 asociated cytokine levels, a change in antigen specific T-cell reactivity, a change in Th1 associated cytokine levels and any combination thereof.

33. The use according to claim 32 wherein the agent decreases the production of Th1 associated cytokines.

34. The use according to claim 33 wherein the Th1 associated cytokine is IFNγ.

35. The use according to claim 32 wherein the agent increases the production of Th2 associated cytokines.

36. The use according to claim 35 wherein the Th2 associated cytokine is selected from the group consisting of IL-4 and IL-10 cytokines.

37. The use according to claim 31 wherein the agent is capable of preventing the onset of insulin dependent diabetes mellitus (IDDM).

38. The use according to claim 37 wherein the agent is co-administered with an autoantigen.

39. The use according to claim 38 wherein the autoantigen is selected from the group consisting of GAD, GAD65, IAA and insulin.

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40. The use according to claim 39 or claim 40 wherein the agent is EtxB.

41. The use according to claim 39 wherein the agent is capable of treating pancreatic islet inflammation or reducing the incidence of IDDM.

42. The use according to claim 41 wherein the agent is EtxB.

43. A method according to claim 14 wherein the agent causes a change in cytokines associated with T regulatory cell.

44. A method according to claim 43 wherein the cytokines are selected from the group consisting of IL-10 and TGFβ and any combination thereof.

45. The use according to claim 32 wherein the agent causes a change in cytokines associated with T regulatory cell.

46. The use according to claim 45 wherein the cytokines are selected from the group consisting of IL-10 and TGFβ and any combination thereof.